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EXAMINER

THANH, LOAN H

ART UNIT	PAPER NUMBER
	3763

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/557,007	RICCI, DONALD R.
	Examiner LoAn H. Thanh	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 April 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-59 is/are pending in the application.

4a) Of the above claim(s) 4-8, 12-15, 19-23, 27-30, 34-38, 42-45, 50, 53 and 58 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3, 9-11, 16-18, 24-26, 31-33, 39-41, 46-49, 51, 52, 54-57 and '59 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 20 April 2000 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,7.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Election/Restrictions

Claims 4-5,19-20,34-35,50,58 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species , there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Further, claims 6-8, 12-15,21-23, 27-30,36-38,42-45,53 are further withdrawn from consideration because they are directed at non-elected embodiment.

Applicant's election with traverse of species I (fig.1) and subspecies B(fig. 4) in Paper No. 6 is acknowledged. The traversal is on the ground(s) that a search of the art will necessarily include a search of the art for the other species and that the burden on the Examiner to examine all the claims in a single application is less than the burden on the applicant to prosecute more than one application. This is not found persuasive because there is no measure of the burden for the examiner compared to the applicant. Further, applicant is reminded that if a generic claim is finally held allowable, the dependent claims **may** be brought back in for consideration at the time of issue. (See page 3 , paragraph 1 of the last office action (paper no. 5). The election of species is considered to be appropriate and the proper traversal is to traverse that the application has no patentably distinct species. If that is the case, applicant is directed to see page 3, paragraph 2 of the last office action (paper no. 5).

The requirement is still deemed proper and is therefore made FINAL.

An action on the merits now follows.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, various densities of the tube (cl. 51) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 52 and 55 objected to because of the following informalities:

Claim 52 appears to be incomplete. It is not clear what is further limiting the claim after "for" on page 10 of pre-amendment "a" filed 03/19/01.

Claim 55, "wo" in line 2 is misspelled. It should be "two".

Appropriate correction is required.

Claims 49 and 57 have the term " as narrower as" which is vague . Applicant is suggested to claim a slit which "as narrow as". For the purpose of art rejection it is interpreted "as narrow as" (i.e. the same)

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gharibadeh et al. (U.S. Patent No. 5,458,613).

Gharibadeh et al. discloses a balloon catheter with an opening and slit-forming region disposed longitudinally in the tubular member. For a guidewire (30 or 31) to be separated from the second lumen. Slit forming region can be considered as 17 or 26 where applicable. Further an adapter slit in the adapter region at the proximal portion of the device. See figures 1-7. With respect to the lumens being disposed in a substantially solid lumen, applicant is requested to look at figures 3-7. In as much as applicant has claimed the substantially solid tubular member, Gharibadeh et al. has also shown.

Claim Rejections - 35 USC§ 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-18,24-26 are rejected under 35 U.S.C. 103 as being unpatentable over Gharibadeh et al. (U.S. Patent No.5,458,1995) .

Gharibadeh et al. discloses the invention substantially as claimed. See above. However, Gharibadeh et al. does not disclose a guide catheter. It is common knowledge in the prior art to utilize a guide catheter with a balloon catheter in the analogous art of balloon catheters for the purpose of aiding in the placement of the balloon catheter by using a delivery sheath. Further, it does not appear that this feature of a guide catheter would make the claim patentable.

Claims 31-33,39-41,46-49,52, 54-57,59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadeh et al. (U.S. Patent No. 5,458,613) in view of Barry (U.S. 5,685,847).

Gharibadeh et al. disclose the invention substantially as claimed. Gharibadeh et al. disclose a tubular member (11), an inflatable balloon (13), a first lumen (12), a second lumen (14 and/or 20) and a guidewire (30 and/or 31). Gharibadeh et al. show a slit (24,26) and an adapter (having a first and second arm (33,35)). The adapter slit is considered to be either the insert slit (39) or the adapter slit (38). Upon closer examination of the reference, Gharibadeh et al. disclosed (6:60-710) that the adapter (33,35) has a straight slit (38) along the entire length from the proximal to the distal end of the adapter. As to the limitation that the adapter slit is narrower than the guidewire diameter throughout the length of the adapter, the Examiner is directing applicant to fig. 2 and more specifically to fig. 3. Fig. 3 clearly shows the slit to be narrower than the guidewire and fig. 2 clearly shows the adapter slit to be throughout the length of the

adapter (along 35). Gharibadeh et al. however does not teach a stent mounted on the balloon. Barry teaches a balloon catheter for deploying a stent. It is well known in the art to use balloon catheters to deliver stents. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the balloon catheter of Gharibadeh et al. as taught by Barry in order to deploy stents.

With respect to claims 46, 47, 56, the straight slit is considered to be shown in figure 2. The adapter being 35 with the straight slit.

Claim 51 is rejected under 35 U.S.C. 103 as being unpatentable over Gharibadeh et al. (U.S. Patent No.5,458,1995) .

Gharibadeh et al. discloses the invention substantially as claimed. See above. However, Gharibadeh et al. does not disclose various densities in the tube. It is common knowledge in the prior art to vary the densities of the tube in order to better maneuver the catheter through the winding paths of the body vessels. Further, it does not appear that this feature of a guide catheter would make the claim patentable.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3,9-11,16-18,24-26, 31-33,39-41, 46-49,51-52,54-57,59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-26,30,31,33-39,41-47,49-50 of copending Application No. 09/501981. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are a broader recitation of the invention than that of the 09/501981 application, including all of the same limitations. The claims of the application claim a balloon catheter comprising a tubular member, a balloon, 2 lumen and an adapter. The 09/501981 claims recite a balloon catheter, a tubular member, 2 lumen and a stent. The claims of the present application are broader and are met by the narrower 09/501981 claims (the 09/501981 claims contain all the limitations of the present application claims).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Johnson et al. (U.S. Patent No.5290232) further supports a balloon catheter having a straight adapter slit for removal of the guidewire.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT